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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/784,842 | 02/23/2004 | Adela Mora-Gutierrez | 017575.0924 (TAMUS 1492) | 1473 |
| 5073 75 | 90 09/28/2004 | | EXAMINER | |
| BAKER BOTTS L.L.P. | | | ANTHONY, JOSEPH DAVID | |
| 2001 ROSS AV | ENUE | | [| |
| SUITE 600 | | | ART UNIT | PAPER NUMBER |
| DALLAS, TX | 75201-2980 | 1714 | | |

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|--|--|---|--------------|-------------|--|--|--|
| Office Action Summary | | 10/784,842 | MORA-GUTIERR | F7 FT AI | | | |
| | | Examiner | Art Unit | L& L I /7L. | | | |
| | | Joseph D. Anthony | 1714 | | | | |
| | The MAILING DATE of this communication app | | | dress | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1)[| Responsive to communication(s) filed on | <u>.</u> . | | | | | |
| 2a) <u></u> □ | This action is FINAL . 2b)⊠ This | action is non-final. | | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositi | on of Claims | | | | | | |
| 4) ☐ Claim(s) 1-43 is/are pending in the application. 4a) Of the above claim(s) 21-41 is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-20,42 and 43 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Applicati | on Papers | | | | | | |
| 9)[| The specification is objected to by the Examine | r. | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | <i>y</i> | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| Attachment | (s) | | | | | | |
| 2) 🔲 Notice 3) 🔲 Inform | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | te |)-152) | | | |

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-20 and 42-43, drawn to an anti-oxidant composition, classified in class 252, subclass 400.21.
- II. Claims 21-41, drawn to a microemulsion or nanoemulsion anti-oxidant composition, classified in class 516, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and II are patentable distinct because invention II has the specific physical property of being a microemulsion or nanoemulsion that imparts to the anti-oxidant composition such properties as a homogeneous nature that remains as is without separation of the individual components. Invention I on the other hand does not have to be in emulsion form at all, and thus can be present as a muti-phase composition.
- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 5. During a telephone conversation with Michelle M. Lecointe on 09/20/04 a provisional election was made without traverse to prosecute the invention of Group I,

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claims 1-20 and 42-43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 1, 14, 16-19, and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by ANTRIM et al. U.S. Patent Number 4,963,385.

Antrim et al. teach stabilized food emulsions containing highly unsaturated oils.

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The emulsions use a stabilizer system in the water phase which comprises either a sugar or sugar alcohol, or a sugar or sugar alcohol and a metal-ion chelator, see abstract, column 1, lines 31-38, column 2, line 20 to column 3 line 46. Non-reducing sugars and sugar alcohols (e.g. maltose, sucrose, lactose, mannitol, sorbitol and xylitol) are directly disclosed by the patent as effective stabilizers against oxidation of highly unsaturated fatty acids or their derivatives, see column 3, lines 48-66. Applicant's claims are deemed to be anticipated over examples 4, 5, 9, 10 and 12.

10. Claims 4-5 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious ANTRIM et al. U.S. Patent Number 4,963,385 optionally in view of BUIKSTRA et al. U.S. Patent Number 5,650,190 for claims 4-5 only.

Antrim et al has been described above and is deemed to anticipate applicants' claims 4-5, and 15 for the same reasons claims 1, 14, 16-19 and 42-43 are anticipated. In the alternative, it is unclear from the Antrim et al reference: 1) if the triglycerides used in the examples actually contain medium-chain triglycerides, and 2) if the phospholipids supplied by the lecithin component actually come from egg yolks or soybeans or are from another source.

It would have been obvious for one having ordinary skill in the art to actually use medium-chain triglycerides in Antrim et al's emulsions since they are deemed to come within the broad disclosure of the patent to the use of oils that contain triglycerides, are so well known in the art, and optionally in view of Buiskstra et al who teaches heat

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stabilized food oil-in-water emulsions of unsaturated oils that comprise medium-chain triglycerides, see abstract, column 3, lines 40-45 and example 6. It would also have been obvious to one having ordinary skill in the art to use phospholipids derived from egg yolks or soybeans since sources for phospholipids are extremely well known in the art. In any case, applicant has not shown that the source of the phospholipids imparts a patentable distinction.

11. Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over ANTRIM et al. U.S. Patent Number 4,963,385 in view of in view of MUSHER U.S. Patent Number 2,282,815.

Antrim et al has been described above and differs from applicants' claimed invention in that there is no direct disclosure to the further addition to the emulsion of phosphopeptide type compounds (e.g. casin).

Musher teaches stabilization of food type water and oil emulsions containing highly unsaturated oils by using the following stabilization systems: 1) a sugar (e.g. sucrose, maltose, lactose), 2) non-aromatic nitrogen compounds such as casin (which comprises phosphopeptide units) or gelatin (which comprises phosphopeptide units), and/or 3) phosphatide = phospholipids (e.g.e lecithin and cephaline), and 4) optional other adjuvents, see page 1, column 1, lines 1-55 and page 1, column 2, lines 1-37, and page 3, column 2, lines 34-70.

It would have been obvious to one having ordinary skill in the art to use the disclosure of Musher as strong motivation to actually add a non-aromatic nitrogen

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compound, such as casin (which comprises phosphopeptide units) to the emulsion disclosed by Antrim et al since both Antrim et al and Musher are directed to the same end or purpose of stabilizing unsaturated olils in emulsion using sugars, such as non-reducing sugars, as one of the required stabilizing components.

12. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over ANTRIM et al. U.S. Patent Number 4,963,385 in view of DEMICHELE et al. U.S. Patent Number 5,223,285 or KAHN et al. U.S. Patent Number 4,421,778.

Antrim et al has been described above and differs from applicant's claimed invention in that there is no direct disclosure to the further addition of sulfated polysaccharides.

Demichele et al and Kahn et al both teach food products in the form of emulsions that contain highly unsaturated oils and other components such as non-reducing sugars (e.g. sucrose), casin, lecithin, <u>carrageenans</u> (which comprise sulfated polysaccharides) etc., see Table 8 of Demichele et al. and Examples 1-2 of Kahn et al..

It would have been obvious to one having ordinary skill in the art to add carrageenans (which comprise sulfated polysaccharides) to Antrim et al's emulsions since such an additive is directly taught to be a well known additive to food type emulsions as taught by Demichele et al and Kahn et al..

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13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over ANTRIM et al. U.S. Patent Number 4,963,385 in view of CANTE et al. U.S. Patent Number 3,887,715.

Antrim et al has been described above and differs from applicant's claimed invention in that there is no direct disclosure to the further addition of a glycopeptide.

Cante et al teaches that it is well known in the art to use proteose-peptone fractions (e.g. glycopeptide) as highly effective emulsifiers for food type unsaturated oil and water emulsions, see abstract, column 3 lines 11-25, and example 2.

It would have been obvious to one having ordinary skill in the art to add proteosepeptone fractions (e.g. glycopeptide) as highly effective emulsifiers to the emulsions taught by Antrim et al using the disclosure of Cante et al as strong motivation.

14. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over ANTRIM et al. U.S. Patent Number 4,963,385 in view of anyone of the following: KIERULFF et al. U.S. Patent Number 6,298,859 or LINDSAY U.S. Patent Number 4,915,876 or SCHROEDER et al. U.S. Patent Number 5,116,629.

Antrim et al has been described above and differs from applicant's claimed invention in that there is no direct disclosure to the further addition of a polyphenol derived from Solanum melongena.

Kierulff et al teaches catechol and catechol oxidase derived from Solanum melongena as effective antioxidants and enzymes.

Lindsay and Schroeder et al both teach that it is well known in the art to use

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polyphenol type antioxidants (e.g. T-butyl hydroquinone) as stabilizers for foods containing highly unsaturated oils, see abstract and example 1 of Lindsay, or abstract, column 6, lines 7-30 and the examples of Schroeder et al..

It would have been obvious to one having ordinary skill in the art to add polyphenol (e.g. catechol or catechol oxidase) derived from Solanum melongena to Antrim et al's emulsions since Kierulff et al. discloses catechol and/or catechol oxidase as well known antioxidant additive as taught by Kierulff et al.. In the alternative it would have been obvious to one having ordinary skill in the art to use the disclosure of Lindsay or Schroeder et al as motivation to added t-butyl hydroqinone as an additional effective antioxidant stabilizer to Antrim et al's emulsions.

The fact that neither Lindsay or Schroeder et al discloses generating their t-butyl hydroqinone from a Solanum melongena source is deemed to be moot since applicant's claims are drawn to a product and not to methods of producing the individual components that make up the claimed product.

15. Claims 1-3, 6-7, 9, 16 and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by KAHN et al. U.S. Patent Number 4,421,778.

Kahn et al teaches freezer stable whipped ice cream and milk shake food products, see abstract, column 4, line 10 to column 5, line 56 and claim 12. Applicants' claims are deemed to be anticipated over examples 1-2 which comprise in part: nonfate dry milk (a source of casin, casin comprises phosphopeptides), sucrose (a non-reducing sugar), Seakem C= calcium carrageeman (comprises sulfated polysaccharide), D-23-A

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(a source of Dutch cocoa powder, soybean and coconut oils (sources of highly unsaturated oils), etc..

16. Claims 4-5, 8, and 10-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious KAHN et al. U.S. Patent Number 4,421,778.

Kahn et al has been described above and applicants' claims are deemed to be anticipated over Examples 1-2. In the alternative, Kahn may differ from applicants' claimed invention in the following ways: 1) it is unclear if Examples 1-2 have medium-chain triglycerides, and 2) it is unclear if the casin component used in examples 1-2 encompasses applicants' claimed casin components..

It would have been obvious to one having ordinary skill in the art to use the medium-chain triglycerides in the food emulsions taught by Kahn et al since such medium-chain triglycerides are deemed to be a component found within soybean oils and/or coconut oils. In any case medium-chain triglycerides are well known fats used in al sorts of edible food emulsions in the art. Finally, applicants' claimed casin type components are deemed to be obvious over the disclosure of Kahn et al because such casins are known components of milk and would thus be obvious to use in Kahn et al's freezer stable whipped ice cream and milk shake food products.

17. Claims 1-6, 14, 16-18 and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by DEMICHELE et al. U.S. Patent Number 5,223,285.

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Demichele et al teach nutritional food products for pulmonary patients in the form of emulsions that contain highly unsaturated oils and other components such as non-reducing sugars (e.g. sucrose), acid casin and calcium caseinate (both comprise phosphopeptides), lecithin (comprises phosphlipids), carrageenans (which comprise sulfated polysaccharides) etc., see abstract, column 16, line 56 to column 17, line 61. Applicants' claims are deemed to be anticipated over the compositions set forth in Table 8.

18. Claims 7-12, 15, and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DEMICHELE et al. U.S. Patent Number 5,223,285.

Demichele et al has been described above and applicant's claims are deemed to be anticipated over Table 8. In the alternative, Demichele et al may differ from applicants' claimed invention in the following ways: 1) it is unclear if the acid casin and calcium caseinate components overlap applicants' claimed casin components of claims 5-12, 2) it is unclear if Table 8 teaches the use of phospholipids derived from egg yolks or soybeans as set forth in applicants' claim 15, and 3) Table 8 teaches the use of sodium citrate instead of citric acid.

It would have been obvious to one having ordinary skill in the art to use casin additives that read on applicant's claimed casin components since such are encompassed by the broad disclosure of the patent. In any case, a well known source of casin is milk which comprised applicant's claimed casin components to one degree or

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another. Whether or not, Table 8 teaches the use of phospholipides derived from egg yolks or soybeans, it would have been obvious to use such sources since they are deemed come within the broad disclosure of the patent. In any case, such is deemed to be most since applicants' claims are not directed to the source of producing the individual components that make up the composition. Furthermore, the use of citric acid in lue of or in combination with, sodium citrate is deemed to be well within the disclosure of the patent.

19. Claims 1-3, 13, 16, and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by CANTE et al. U.S. Patent Number 3,887,715.

Cante et al teaches edible stabilized polyunsaturated emulsions prepared by using proteose-peptone fractions (e.g. glycopeptide) of bovine milk as highly effective emulsifiers for food type unsaturated oil and water emulsions, see abstract, column 3 lines 11-25, and example 2. The disclosed edible emulsions may also comprise additional ingredients such as sugars (e.g. sucrose), casin (comprises phosphopeptides), carrageenan (comprises sulfated polysaccharide) gums, flavors etc.. Applicant's claims are deemed to be anticipated over Example 2.

20. Claims 4-12, 14-15, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over CANTE et al. U.S. Patent Number 3,887,715 individually in view of anyone of the following: BUIKSTRA et al. U.S. Patent Number 5,650,190 (for claims 4-5 only) or CHANG et al. U.S. Patent Number 5,077,069 (for claims 14-15 and 17-19) or

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[KIERULFF et al. U.S. Patent Number 6,298,859 or LINDSAY U.S. Patent Number 4,915,876 or SCHROEDER et al. U.S. Patent Number 5,116,629] (for claim 20 only).

Cante et al. and all secondary references have been described above. Cante et al differ from applicants' claimed invention in the following ways: 1) there is no direct disclosure to the use of medium-chain triglycerides, 2) there is no direct teaching (i.e. by way of an example) to wherein a casin compound is actually used in the disclosed emulsions in combination with a non-reducing sugar (e.g. sucrose), 3) there is not a direct disclosure to the further addition of applicants' claimed phospholipids and chelating agents (e.g. citric acid), and 4) there is not a direct disclosure to the further addition of a polyphenol type antioxidant to the disclosed compositions.

It would have been obvious to one having ordinary skill in the art to use the disclosure of Buikstra et al as strong motivation to actually use medium-chain triglycerides in the emulsions taught by Cante since such medium-chain triglycerides are taught to be well known triglycerides in edible emulsions products. Likewise it would have been obvious to actually use a casin y/type component in combination with a non-reducing sugar (e.g. sucrose) since such is strongly suggested by the Cante et al reference itself. Furthermore, it would have been obvious to use the disclosure of Chang et al as strong motivation to actually incorporate additional additives such as phospholipids and chelating agents (e.g. citric acid) into Cante et al's edible emulsions for the benefits that such additives give to such compositions. Furthermore, it would have been obvious to one having ordinary skill in the art to add a polyphenol antioxidant as a further stabilizer component to the emulsion disclosed by Cante et al. using anyone

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of the disclosures of Kierulff et al., Lindsay or Schroeder et al. as strong motivation.

Prior-Art Cited But Not Applied

21. Any prior-art reference which is cited on FORM PTO-892 but not applied, is cited only to show the general state of the prior-art at the time of applicant's invention.

Examiner Information

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Joseph D. Anthony whose telephone number is (571) 272-1117. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (571) 272-1119. The centralized FAX machine number is (703) 872-9306. All other papers received by FAX will be treated as Official communications and cannot be immediately handled by the Examiner.

Joseph D. Anthony Primary Patent Examiner Page 13

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